

that constitute a trade secret or confidential commercial or financial information as defined in §20.61 only if the person has been appointed as a special Government employee under §14.80(b).

(b) A nonvoting member of an advisory committee is subject to, and shall abide by, all rules and regulations adopted by FDA and the committee.

(c) It is the responsibility of the nonvoting consumer and industry members of an advisory committee to represent the consumer and industry interests in all deliberations.

(1) A nonvoting member does not represent any particular organization or group, but rather represents all interested persons within the class which the member is selected to represent. Accordingly, an interested person within the class represented by that nonvoting member may, upon request, have access to all written statements or oral briefings concerning the committee prepared by the nonvoting member for distribution to any person outside the committee. When documents are prepared with non-Government funds, persons desiring copies may be required to pay a reasonable fee to cover printing and similar costs.

(2) The nonvoting member reviews all official committee minutes to assure their completeness and accuracy.

(3) The nonvoting member acts as a liaison between the committee and the interested persons whom that member represents, and transmits requests for information from the committee and relevant information and views to the committee. The nonvoting member takes the initiative in contacting interested persons whom the member represents to seek out relevant information and views and to relate the progress of the advisory committee.

(4) A nonvoting industry member represents all members of the industry, and not any particular association, company, product, or ingredient. If a matter comes before the committee that directly or indirectly affects the company employing the nonvoting industry member, the member shall so inform the committee but need not be absent during the discussion or decline to participate in the discussion. A nonvoting industry member may not discuss the company's position as such,

but may discuss any matter in general terms. All presentations and discussions of scientific data and their interpretation on behalf of a company will occur in open session, except as provided in §14.25(c).

(5) A nonvoting member of an advisory committee may not make any presentation to that advisory committee during a hearing conducted by that committee.

(6) Although a nonvoting member serves in a representative capacity, the nonvoting member shall exercise restraint in performing such functions and may not engage in unseemly advocacy or attempt to exert undue influence over the other members of the committee.

(d) A nonvoting member of an advisory committee may be removed by the Commissioner for failure to comply with this section as well as §14.80(f).

#### **§ 14.90 Ad hoc advisory committee members.**

In selecting members of an ad hoc advisory committee, the Commissioner may use the procedures in §§14.82 and 14.84 or any other procedure deemed appropriate.

#### **§ 14.95 Compensation of advisory committee members.**

(a)(1) Except as provided in paragraphs (a) (2) and (3) of this section, all voting advisory committee members shall, and nonvoting members may, be appointed as special Government employees and receive a consultant fee and be reimbursed for travel expenses, including per diem in lieu of subsistence, unless such compensation and reimbursement are waived.

(2) Members of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) are not appointed as special Government employees. Any member of TEPRSSC who is not a Federal employee or member of the uniformed services, including the Commissioned Corps of the Public Health Service, shall receive a consultant fee and be reimbursed for travel expenses, including per diem in lieu of subsistence, unless such compensation and reimbursement are waived.

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(3) Voting and nonvoting advisory committee members who are members of the uniformed services, including the Commissioned Corps of the Public Health Service, provide service on Food and Drug Administration advisory committees as part of their assigned functions, are not appointed as special government employees, but are reimbursed by the Food and Drug Administration for travel expenses.

(b) Notwithstanding the member's primary residence, an advisory committee member, while attending meetings of the full committee or a subcommittee, will be paid whether the meetings are held in the Washington, DC, area or elsewhere.

(c) A committee member who participates in any agency-directed assignment will be paid at an hourly rate when doing assigned work at home, a place of business, or in an FDA facility located within the member's commuting area, and at a daily rate when required to travel outside of that commuting area to perform the assignment. A committee member will not be paid for time spent on normal preparation for a committee meeting.

(1) An agency-directed assignment is an assignment that meets the following criteria:

(i) An activity that requires undertaking a definitive study. The activity must produce a tangible end product, usually a written report. Examples are:

(a) An analysis of the risks and benefits of the use of a class of drugs or a report on a specific problem generated by an IND or NDA;

(b) The performance of similar investigations or analysis of complex industry submissions to support advisory committee deliberations other than normal meeting preparation;

(c) The preparation of a statistical analysis leading to an estimate of toxicologically safe dose levels; and

(d) The design or analysis of animal studies of toxicity, mutagenicity, teratogenicity, or carcinogenicity.

(ii) The performance of an IND or NDA review or similar review.

(2) A committee member who undertakes a special assignment, the end product of which does not represent the end product of the advisory committee, but rather of the committee member's

own assignment, can be compensated. Should this preparatory work by members collectively result in an end product of the committee, this is to be considered normal meeting preparation and committee members are not to be compensated for this work.

(d) Salary while in travel status is authorized when a committee member's ordinary pursuits are interrupted for the substantial portion of an additional day beyond the day or days spent in performing those services, and as a consequence the committee member loses some regular compensation. This applies on weekends and holidays if the special Government employee loses income that would otherwise be earned on that day. For travel purposes, a substantial portion of a day is defined as 50 percent of the working day, and the traveler will be paid at a daily rate.

[44 FR 22351, Apr. 13, 1979, as amended at 53 FR 50949, Dec. 19, 1988]

### Subpart F—Standing Advisory Committees

#### § 14.100 List of standing advisory committees.

Standing advisory committees and the dates of their establishment are as follows:

(a) *Office of the Commissioner—*

(1) *Board of Tea Experts.*

(i) Date established: March 2, 1897.

(ii) Function: Advises on establishment of uniform standards of purity, quality, and fitness for consumption of all tea imported into the United States under 21 U.S.C. 42.

(2) *Science Board to the Food and Drug Administration.*

(i) Date established: June 26, 1992.

(ii) Function: The board shall provide advice primarily to the agency's Senior Science Advisor and, as needed, to the Commissioner and other appropriate officials on specific complex and technical issues as well as emerging issues within the scientific community in industry and academia. Additionally, the board will provide advice to the agency